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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	:	
GILBERT V. LEVIN	:	Group Art Unit: 1623
Serial No.: 09/811,654	:	Examiner: H. Owens, Jr.
Filed: March 20, 2001	:	
For: USE OF TAGATOSE IN PROMOTING CARDIOVASCULAR HEALTH	:	

APPEAL BRIEF

Mail Stop Appeal Briefs – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

1. Real Party In Interest

The real party in interest in this appeal is Spherix Incorporated, formerly Biospherics Incorporated.

2. Related Appeals and Interferences

There are no related appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

3. Status of Claims

The finally rejected claims are claims 1-7. These are the claims appealed. The appealed claims are set forth in the Appendix.

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4. Status of Amendments

No amendment has been filed subsequent to final rejection.

5. Summary of Invention

Appellant has made the discovery that a mammal in need of treatment to promote cardiovascular health may be treated to promote cardiovascular health by administering to the mammal an efficacious amount of tagatose to raise the HDL level in the mammal. There are two forms of cholesterol, high-density (HDL) and low-density (LDL). HDL, the "good" cholesterol, moves easily through the blood, does not stick to artery walls and carries the cholesterol to the liver for removal. LDL, the "bad" cholesterol contains fat and sticks to arterial walls forming plaque which is a cause of heart disease by restricting blood flow.

6. Issues

The issues presented for review are as follows:

A. Did the Examiner err in rejecting claim 7 under 35 U.S.C. §112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention"?

B. Did the Examiner err in rejecting claims 1-6 under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Zehner et al., U.S. Patent No. 5,356,879?

7. Grouping of Claims

A. As to the rejection of claim 7 under 35 U.S.C. §112, first paragraph, only one claim is subject to this rejection, and, therefore, it stands alone.

B. As to the rejection of claims 1-6, under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Zehner et al., U.S. Patent No. 5,356,879, these claims will stand or fall together.

8. Argument

A. The Rejection Based on 35 U.S.C. §112, First Paragraph

The final Office Action indicates that it is not clear that applicant was in possession of the administration of L-tagatose or a mixture of the two isomers for a method of promoting cardiovascular health. However, the first paragraph on page 2 of the specification clearly states that an efficacious amount of tagatose, i.e., D-tagatose, L-tagatose or a mixture of the two isomers may be administered to a mammal to increase the HDL level of the mammal. Thus, applicant was clearly in possession of the invention of the use of D-tagatose, L-tagatose or a mixture of the two isomers to increase the HDL level of the mammal. No more should be required to comply with 35 U.S.C. 112, first paragraph.

B. The Rejection of Claims 1-6 Under 35 U.S.C. §102(b) or as Obvious Over Zehner et al. U.S. Patent No. 5,356,879

Claims 1-6 stand finally rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Zehner et al. U.S. Patent 5,356,879. Zehner et al. teach a method for preventing the formation of advance glycosylation end-products in a mammal comprising administering to said mammal an effective amount of D-tagatose, see claim 1. In contrast, the claims herein recite "a method for promoting cardiovascular health in a mammal in need of such treatment". While the phrase "a method for promoting cardiovascular health in a mammal" is technically part of the preamble because it appears before the transition word "comprising", there should be no question in this case that the phrase should be treated as a

claim limitation, Rapoport v. Dement, 59 USPQ2d 1215, 1219 (US Court of Appeals for the Federal Circuit 2001). Moreover, without treating the phrase "promoting cardiovascular health in a mammal" as a claim limitation, the phrase "in need of such treatment" would not have a proper antecedent basis, Rapoport v. Dement, supra, at 1219.

The final Office Action cites *In re Nowitzki, 26 USPQ2d, 1389 (Board of Patent Appeals and Interferences 1993)*, for the proposition that the administration of tagatose by Zehner et al. to reduce the occurrence of complications such as atherosclerosis due to accumulated glycosylation end-products inherently anticipates applicant's intended use for increasing HDL and would clearly promote cardiovascular health. In that case, the Board found that the process performed by the reference "inherently and necessarily constitutes a method for protecting a plant from plant pathogenic nematodes". However, a person practicing the invention disclosed by Zehner et al. would not necessarily and inherently promote cardiovascular health in the individual being treated. Further, the patient being treated for preventing the formation of advanced glycosylation end-products by the method described by Zehner et al. would not necessarily be a patient in need of treatment for promoting cardiovascular health as required by the appealed claims.

Thus, the claims of the Zehner et al. patent address the prevention of the formation of glycosylation end-products for the purpose of delaying aging. The present application addresses the promotion of cardiovascular health by increasing the high density lipid (HDL – or "good") fraction of cholesterol, thereby reducing the risk of blocked arteries. There is no identity to these two inventions. While one might construe that any promotion of health will delay aging, this is a far less specific effect than is the prevention of glycosylation, nor does the former imply the latter. The latter cross-links protein molecules constituting muscle and brain tissue, thereby slowing down and interfering with the transmissions of signals and the response of muscles.

These effects constitute aging. One skilled in the art possessing the knowledge that tagatose will reduce glycosylation would not conclude that it would also increase HDL. There is nothing in the art establishing such a relationship. Glycosylation concerns protein, HDL is a lipid, i.e., two very different types of compounds both chemically and functionally.

9. Conclusion

For the foregoing reasons, it is respectfully submitted that both of the rejections set forth by the Examiner in the Final Rejection dated March 11, 2003 should be reversed. Such favorable action is earnestly solicited.

Respectfully submitted,

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Dated: July 31, 2003

APPENDIX

1. A method for promoting cardiovascular health in a mammal in need of such treatment comprising administering to said mammal an efficacious amount of tagatose to raise the HDL level in the mammal.

2. The method of claim 1 wherein the mammal is a human.

3. The method of claim 1 wherein from 50 to 1,500 mg/kg body weight/day is administered to said mammal.

4. The method of claim 1 wherein the prescribed dose is taken every day.

5. The method of claim 1 wherein the prescribed dose is taken every other day.

6. The method of claim 1 wherein said tagatose is used in combination with a medication known to be useful in promoting cardiovascular health.

7. The method of claim 1 wherein the tagatose is D-tagatose, L-tagatose, or a mixture of the two isomers.